

SPL ER/DL Team Meeting

June 23, 2010

Agenda/Minutes

1. API manufacturer – including establishment information as part of drug listing -- Kathleen Parker
 - a. Question FDA has asked them to include API establishments in the drug listing data elements. What do other pharma do?
 - b. Comments from several pharma: API mfg establishments are included as part of the drug listing data elements – for both corporate establishments as well as third party suppliers of API. This is consistent with FDA training on completion of drug listing data elements.
2. Kits—getting questions from DRLS staff to provide specifics on the manufacturers for each of the components of a kit.
 - a. This has been observed by several other participants.
 - b. This is also an issue with labels that contain multiple dosage forms – that are manufactured at different establishments.
 - c. Terry Brunone commented that SPL currently can't capture this level of detail, but that the SPL could be modified to accommodate this in the future
3. Images on package labels...readability- Howard Shatz
 - a. Two clients are having spl rejected because images are not legible. How are companies dealing with problem of readability and including full package images in PDP section for large packages (1000 pixels wide)
 - b. Legibility has been an issue since these were required to be provided in the SPL
 - c. In today's Q&A, Lonnie suggested that they cut the image in half.
 - d. From the Step by Step instructions (Section 4.7): The content of the labeling provided with drug listing (e.g., professional labeling (package insert), consumer labeling, carton labels and container labels) is included in the same SPL file as the other drug listing information. Carton and container labels include the content of the Drug Facts or equivalent for animal drug products and the content of the Principal Display Panel including the image of the entire label as a single jpg file.
4. Do companies also submit the carton and label as part of the eCTD?
 - a. Consensus of companies attending the call: using conservative practice -- submitting all cartons/labels to review division when there are changes.
5. Listing NDCs not available for sale - Michelle Halliez
 - a. BMS recently received request from CMS group (pricing) to include different NDC codes for the inner and outer packaging components. The inner package is not a saleable unit. They called David Maczyk. He confirmed that they should list the inner package in order to address the CMS needs – ie a workaround on the pricing side.
 - b. Samples are also included in drug listing data elements.
 - c. Concern is that pricing groups will not be able to differentiate between salable and non-salable unit.

6. Update from leadership team - Terry Brunone
 - a. New leadership at DRLS group – Paul Loebach. (See #9 below.) It would be nice to discuss with him key issues related to the use of SPL and current regs/guidelines -- Need to be very conscious that companies are still having problem with importing. Need to effectively manage of SPL education issues when companies are filing according the regulations/guidelines.
 - b. HL7 review of R5 schema. Still has no impact on SPL. However HL7 is a huge standard and includes a technology specification. It is possible that FDA may have to change their schema to utilize this standard. Tech team is reviewing this situation and is putting forth a proposal to continue to use the current technology concurrently with the implementation of the newer standard.
 - c. Devices: Myron is monitoring. Moving slowly.
 - d. Federal register notices related to Indexing
 - e. Where to put the spl link within the eCTD backbone???? Terri to contact Ginny Ventura within the FDA. Will come back for future discussion.
 - f. If anyone is having Er/DL problems with CBER products, they should coopy vada.perkins@fda.hhs.gov
7. New UNII Substance Interface
 - a. Advantages: Good resource, one place to go. Links to other chemical links.
 - b. Caution – couldn't find appropriate UNII for certain products:
 - i. Compressible sugar is a multiple ingredient.
 - ii. Vaccine. Could find UNII name by code, but not by the number by entering the name.
 - c. Still using spreadsheet with site as confirmation
8. Recent NLM posting issues:
 - a. Deleted SPL from NLM when only 1 product (of several) in the SPL was being delisted
 - b. Kept SPL when all products had market end dates.
 - c. NLM was very responsive to correct these situations
 - d. Be sure to monitor these situations.
9. Plan to invite new DRLS lead (Paul Loebach paul.loebach@fda.hhs.gov) to discuss our general drug listing questions. Please provide questions that we can use in the discussion. Terry will invite him to the July 21st meeting. Pat will send out request for questions, and then tabulate/send him a list 2 weeks before the call. Start of the list:
 - a. Why do we get asked for a new Labeler Code Request when we ask for an FEI?
 - b. What's up with the Imports Inspectors – do they have access to our data? Elist?
 - c. How can we best provide details to DRLS staff related to questions when the SPL includes multiple establishments included in the SPL – eg different manufacturers for individual parts of the kit or different product formulations/pack sizes. This could involve changes to SPL data standards.
 - d. We are being asked by DRLS staff to provide NDC codes (and thus drug list) for inner and outer packaging components and individual parts in a kit. We have concerns about drug listing non-saleable units. Please explain the rationale for this.